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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/666,581 | 09/18/2003 | Yoshikazu Tobinaga | 27698.001 | 9168 |

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| EXAMINER | |
|---|---|
| AHMED, AAMER S | |
| **ART UNIT** | **PAPER NUMBER** |
| 3763 | |

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/666,581 | TOBINAGA ET AL. | |
| | Examiner | Art Unit | |
| | Aamer S. Ahmed | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) 11 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 and 12-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

The declaration under 37 CFR 1.132 filed 09/15/2005 is insufficient to overcome the rejection of claim 11 (now cancelled and incorporated into amended claim 1) based upon Park et al in view of D'Ussel as set forth in the last Office action because: Park teaches a microneedle device and D'Ussel teaches a method of making needles of sugar. Furthermore D'Ussel discloses that needle tips made of sugar, it would be obvious to one having ordinary skill in the art at the time of invention by applicant to form the rest of the needle of sugar.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 7-10, 14-16 and 10-30, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1) in view of D'Ussel (Pub. No.: US 20040010237 A1). As to Claim 1, Park describes an applicator for applying functional substances into human skin, comprising: a base, a plurality of microneedles fixed to the base and projecting therefrom a distance sufficient to penetrate into the skin, the microneedles being made of a material that is capable of disintegration and dispersion into the skin, and a functional substance carried by the microneedles for delivery by the microneedles into the skin. (See Figure 5). Park describes an applicator for applying functional substances into human skin as mentioned above. Park fails to disclose that the needle material is substantially sugars, which dissolve in the human body. D'Ussel describes a needle made substantially of sugars that dissolves within the human body. (See Page 1 Paragraph 14). It would have been obvious to

one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the sugar needle of D'Ussel in order to make a more biodegradable needle of the type disclosed by D'Ussel.

Similarly Park describes in Claim 2, as an applicator as described above, and further characterized by having the functional substance distributed in the material of the microneedles. (See Page 3 paragraph 0046).

Moreover as to Claim 3, Park describes that the functional substance is distributed homogeneously throughout the microneedles. (See Column 3 paragraph 0046).

In addition, as to Claim 4, Park recites that the functional substance is encapsulated in the microneedles. (See Page 3 Paragraph 0045).

Furthermore, as to Claim 5, Park teaches that the base and microneedles are integrally molded from the same material. (See Page 3 Paragraph 0040).

Also, as to Claim 7, Park discloses that the microneedles are generally cone shaped. (See Figure 5).

Similarly, as to Claims 8, 9 and 10, Park describes that the microneedles may be square, polygonal or elliptical in cross-section. (See Page 4 Paragraph 0054).

Furthermore, as to Claim 14, Park discloses that the microneedles have tips that are knife-shaped. (See Figure 5).

In addition, as to Claim 15, Park discloses that the microneedles contain microcontainers containing a functional substance, and the microcontainer is contained within the microneedle. (See Figure 3).

Moreover, as to Claim 16 and 34, Park discloses that the microneedles are formed with barbed tips and the microcontainers are disposed in the barbed tips. (See Figure 3).

Also as to Claim 19, Park discloses that the microneedles project from said base a distance sufficient to penetrate the stratum corneum. (See Page 9 Paragraph 0119 ).

Furthermore, as to Claim 20 Park teaches that the microneedles project approximately 0.5 to 500μm from the base. (See Page 5 Paragraphs 0057-0059).

Similarly, as to Claims 21,22, 23, 24 and 32 Park describes that the microneedles are generally cone shaped, (See Figure 5), with a diameter as base approximately 0.1 to 100μm and the microneedles that are square, polygonal or partially elliptical in cross-section having sides or diameters approximately 0.1 to 100μm at base. (See Page 5 Paragraphs 0057-0059).

In addition, as to Claim 25, Park describes that the microneedles are of sufficient projection to penetrate the dermis. (See Page 8 Paragraph 101).

Moreover as to Claim 26 Park discloses that the microneedles project approximately 500 to 5,000μm from the base. (See Page 5 Paragraphs 0057-0059).

Similarly, as to Claims 27-30, Park describes, that the microneedles are generally cone shaped, (See Figure 5), with a diameter as base approximately 0.1 to 1,000μm and the microneedles that are square, polygonal or partially elliptical in cross-section having sides or diameters approximately 0.1 to 100μm at base. (See Page 5 Paragraphs 0057-0059).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of D'Ussel. Park et al and D'Ussel describe the device as disclosed above in reference to claim 1 and substantially as claimed. However neither Park et al nor D'Ussel explicitly disclose that the sugar is a maltose sugar. Applicant has not disclosed that this specific type of sugar solves any

stated problem or is for any particular purpose over other sugars. Therefore it appears that the needle would perform equally well if made of a sugar as stated by D'Ussel. Accordingly, the use of maltose is deemed to be an obvious design consideration which fails to patentable distinguish over D'Ussel.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1). Referring to claims 6, it would have been an obvious matter of design choice to distribute the functional substance homogeneously throughout the base and microneedles. Applicant has not disclosed that the specific inclusion of the second recess solves any stated problem that invention would perform equally well with the functional substance contained within the microneedle.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1) in view of Arias et al (US 20020133129 A1). Park describes an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1. Park fails to disclose microneedles with a constricted intermediate ends.
Arias does describe microneedles with a constricted intermediate ends. (See Figure 15L).
It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the constricted intermediate end design of Arias in order to make a more breakable microneedle tip of the type disclosed by Arias.

Similarly Claims 13 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1) in view of Arias et al (US 20020133129 A1). Park describes an applicator for applying functional substances into human skin as mentioned

above in reference to Claim 1. Park fails to disclose microneedles with thin outer portions and thick inner portions adjacent the base with the outer portions remaining in the skin.

Arias does describe microneedles with thin outer portions and thick inner portions adjacent the base with the outer portions remaining in the skin. (See Figure 15I).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the varied thickness design of Arias in order to make a more separable microneedle tip of the type disclosed by Arias.

Finally Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (Pub. No.: US 2002/0082543 A1) in view of Sherman et al ('281).

Park describes an applicator for applying functional substances into human skin as mentioned above in reference to Claim 1. Park fails to disclose microneedles having capillary recesses in outer the portions, or capillary recesses extending along a central axis of said microneedles and are open at the outer ends of said microneedles.

Sherman does describe microneedles with capillary recesses in outer the portions and the capillary recesses extending along a central axis of said microneedles and are open at the outer ends of said microneedles. (See 38 Figure 4).

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the applicator for applying functional substances into human skin with the microneedles having capillary recesses in outer the portions as described by Sherman in order to enhance retention of the functional substances for delivery into the skin.

***Response to Arguments***

Applicant's arguments filed 09/15/2005 have been fully considered but they are not persuasive. Applicant argues that the prior art reference D'Ussel does not disclose or suggest a needle made substantially of sugars. However D'Ussel does disclose a portion of the needle made of sugar and it would have been obvious to make the needle substantially of sugars. Furthermore when combined with the prior art reference Park, it would have been obvious to incorporated the sugar needle of D'Ussel with the microneedle device of Park in order to makee a more degradable needle. Furthermore applicant argues that the prior art references do not disclose that the microneedles are restricted intermediate their ends, however Arias does disclose restricted microneedles capable of breaking off. Applicant argues that Park fails to disclose microneedles that are knife-shaped or barbed, however these shapes are disclosed by Park (figures 5 and 3).

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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|---|---|
| U.S. Pub. No. 20030095582A1 | Ackley |
| U.S. Pub. No. 20020138049 A1 | Allen |
| U.S. Pat. No. 6334856 B1 | Allen |
| U.S. Pub. No. 20040146611 A1 | Arias |
| U.S. Pat. No. 6770480 B1 | Canham |
| U.S. Pub. No. 20020193754 A1 | Cho |
| U.S. Pat. No. 6767341 B2 | Cho |
| U.S. Pat. No. 6689100 B2 | Connelly |
| U.S. Pub. No. 20020193729 A1 | Cormier |
| U.S. Pat. No. 6881203 B2 | Delmore |
| U.S. Pat. No. 6780171 B2 | Gabel |
| U.S. Pat. No. 6652478 B1 | Gartstein |
| U.S. Pat. No. 3964482 A | Gerstel |
| U.S. Pub. No. 20030135167 A1 | Gonnelli. |
| U.S. Pat. No. 4206757 A1 | Grandadam |
| U.S. Pub. No. 20040087893 A1 | Kwon |
| U.S. Pat. No. 6113581 A | Levy |
| U.S. Pat. No. 6517521 B1 | Ly |
| U.S. Pub. No. 20030208138 A1 | Olson |

| | |
|---|---|
| U.S. Pub. No. 20030208167 A1 | Prausnitz |
| U.S. Pat. No. 6503231 B1 | Prausnitz |
| U.S. Pat. No. 6611707 B1 | Prausnitz |
| U.S. Pat. No. 6743211 B1 | Prausnitz |
| U.S. Pat No. 6102896 | Roser |
| U.S. Pub. No. 20030199812 A1 | Rosenberg |
| U.S. Pat. No. 6623457 B1 | Rosenberg |
| U.S. Pat. No. 6790372 B2 | Roy |
| U.S. Pat. No. 6835184 B1 | Sage |
| U.S. Pat. No. 4921475 A | Sibalis |
| U.S. Pub. No. 20020099356 A1 | Unger |
| U.S. Pat. No. 6603987 B2 | Whitson |
| U.S. Pat. No. 6558361 B1 | Yeshurun |
| U.S. Pat. No. 6565532 B1 | Yuzhakov |
| U.S. Pat. No. 6256533 B1 | Yuzhakov |
| WO2004000389A2 | Kwon |
| WO98/28037 | Theeuwes |
| DE2825232C2 | Roussel-Uclef |
| DE69720057T2 | Theeuwes et al. |
| DE10065168 | Bracht et al. |
| WO2004/033021A1 | Gonnell |

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. A.

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